

JUN 27 2003

CD HORIZON® Spinal System
Summary of Safety and Effectiveness
May 2003

I. Company: Medtronic Sofamor Danek, Inc. USA
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133

II. Proposed Proprietary Trade Name: CD HORIZON® Spinal System

Regulation Numbers: 888.3050, 888.3060 and 888.3070

Regulation Names: Spinal Interlaminar Fixation Orthosis, Spinal Intervertebral Body Fixation Orthosis, and Pedicle Screw Spinal System.

Codes: KWQ, KWP, MNH and MNI

III. Product Description

The CD HORIZON® Spinal System consists of a variety of rods, hooks, screws, CROSSLINK® plates, staples, and other connecting components, as well as implant components from other Medtronic Sofamor Danek spinal systems, which can be rigidly locked in a variety of configurations, with each construct being tailor-made for the individual case. If necessary, the CD HORIZON® Spinal System can be connected to the VERTEX™ Reconstruction System through a rod connector.

Certain implant components from other Medtronic Sofamor Danek spinal systems can be used with the CD HORIZON® Spinal System. These components include TSRH® rods, hooks, screws, plates, CROSSLINK® plates, connectors, staples and washers; GDLH® rods, hooks, connectors and CROSSLINK® bar and connectors; LIBERTY® rods and screws; DYNALOK PLUS® bolts; and Medtronic Sofamor Danek Multi-Axial rods and screws. Please note that certain components are specifically designed to connect to 4.5mm, 5.5mm, or 6.35mm diameter rods, while other components can connect to both 5.5mm and 6.35mm rods. Care should be taken so that the correct components are used in the spinal construct.

CD HORIZON® hooks are intended for posterior use only. CD HORIZON® staples and CD HORIZON® ECLIPSE® rods and screws are intended for anterior use only. However, for patients of smaller stature, CD HORIZON® 4.5mm rods and associated components may be used posteriorly.

The CD HORIZON® Spinal System implant components are fabricated from medical grade stainless steel described by such standards as ASTM F138 or ASTM F1314 or ISO 5832-1 or ISO 5832-9. Alternatively, the entire system may be made out of medical grade titanium or titanium alloy described by such standards as ASTM F67 or ASTM F136 or ISO 5832-3 or 5832-2. Medtronic Sofamor Danek expressly warrants that these devices are fabricated from one of the foregoing material specifications. No other warranties, expressed or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the MSD Catalog for further information about warranties and limitations of liability. **Never use stainless steel and titanium implant components in the same construct.**

The CD HORIZON® Spinal System also includes anterior staples made of Shape Memory Alloy (Nitinol – NiTi). Shape Memory Alloy is compatible with titanium implants only. **Do not use with stainless steel.**

The purpose of this 510(k) submission is to add components to the existing CD HORIZON® Spinal System.

IV. Indications

The CD HORIZON® system is intended for the following indications:

When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the CD HORIZON® Spinal System is indicated for one or more of the following: (1) degenerative spondylolisthesis with objective evidence of neurologic impairment, (2) fracture, (3) dislocation, (4) scoliosis, (5) kyphosis, (6) spinal tumor, and/or (7) failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the CD HORIZON® Spinal System is indicated for skeletally mature patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (3) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (4) who are having the device removed after the development of a solid fusion mass.

When used as a posterior, non-cervical, non-pedicle screw fixation system, the CD HORIZON® Spinal System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

When used in a percutaneous posterior approach with the SEXTANT instrumentation, the CD HORIZON® Cannulated M8 Multi-Axial Screw components are intended for the following indications:

When used as a pedicle screw fixation system the CD HORIZON® Cannulated M8 Multi-Axial Screw components are also indicated for skeletally mature patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); (d) who are having the device removed after the development of a solid fusion mass.

In addition, when used as a posterior spine thoracic/lumbar system, the CD HORIZON® Cannulated M8 Multi-Axial Screw components are intended for: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e. degenerative scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

The CD HORIZON® ECLIPSE® components are intended for the following indications:

When used as an anterolateral thoracic/lumbar system, the CD HORIZON® Spinal System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis,

and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

In order to achieve additional levels of fixation, the CD HORIZON® Spinal System rods may be connected to the VERTEX™ Reconstruction System with the VERTEX™ rod connector. When connecting to the VERTEX™ Reconstruction System in the cervical spine, components are intended for the following indications:

When intended to promote fusion of the cervical spine and the thoracic spine, (C1-T3), the VERTEX™ Reconstruction System is indicated for the following:

DDD (neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, failed previous fusion and/or tumors.

Hooks and Rods

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

Multi-axial Screws/Lateral Connectors

The use of VERTEX™ multi-axial screws (3.5mm and 4.0mm cancellous, and 4.0mm cortical) is limited to placement in T1-T3 in treating thoracic conditions only. The multi-axial screws are not intended to be placed in the cervical spine.

Titanium ATLAS™ Cable and the CD HORIZON® Spinal System may be used with the VERTEX™ Reconstruction System.

V. Substantial Equivalence

Documentation was provided which demonstrated the CD HORIZON® Spinal System to be substantially equivalent to itself.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2003

Richard W. Treharne, Ph.D.
Senior Vice President, Research and Regulatory Affairs
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K031655

Trade/Device Name: CD Horizon Spinal System
Regulatory Number: 21 CFR 888.3070 (b)(1), 888.3050, 888.3060
Regulation Name: Pedicle screw spinal system, Spinal interlaminar fixation
orthosis, Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MNI, MNH, KWP, KWQ
Dated: May 27, 2003
Received: May 28, 2003

Dear Dr. Treharne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

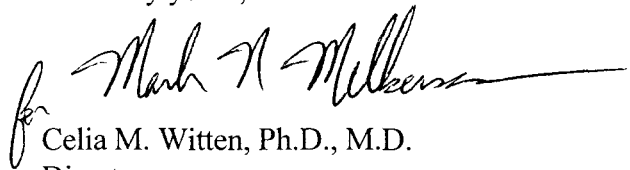
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a long horizontal flourish extending to the right.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031655

Device Name: CD HORIZON® Spinal System

Indications for Use:

The CD HORIZON® system is intended for the following indications:

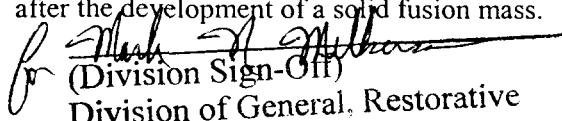
When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the CD HORIZON® Spinal System is indicated for one or more of the following: (1) degenerative spondylolisthesis with objective evidence of neurologic impairment, (2) fracture, (3) dislocation, (4) scoliosis, (5) kyphosis, (6) spinal tumor, and/or (7) failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the CD HORIZON® Spinal System is indicated for skeletally mature patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (3) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (4) who are having the device removed after the development of a solid fusion mass.

When used as a posterior, non-cervical, non-pedicle screw fixation system, the CD HORIZON® Spinal System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

When used in a percutaneous posterior approach with the SEXTANT instrumentation, the CD HORIZON® Cannulated M8 Multi-Axial Screw components are intended for the following indications:

When used as a pedicle screw fixation system the CD HORIZON® Cannulated M8 Multi-Axial Screw components are indicated for skeletally mature patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); (d) who are having the device removed after the development of a solid fusion mass.


(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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510(k) Number K031655

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In addition, when used as a posterior spine thoracic/lumbar system, the CD HORIZON® Cannulated M8 Multi-Axial Screw components are intended for: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e. degenerative scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

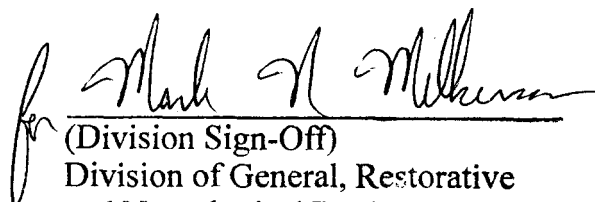
The CD HORIZON® ECLIPSE® components are intended for the following indications:
When used as an anterolateral thoracic/lumbar system, the CD HORIZON® Spinal System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

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NEEDED)

Concurrence of CDRH, Office of Evaluation (ODE)

Prescription Use _____ OR Over-the-counter Use _____
(Per 21 CFR 801.109)

(Optional 1-2-96)


(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number _____

K031655

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